In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: June 27, 2023

TERRY PEDRI, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	No. 18-1077V Special Master Sanders

Leigh Finfer, Muller Brazil, LLP, Dresher, PA, for Petitioner.
Sarah C. Duncan, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION ON ENTITLEMENT[1]

On July 24, 2018, Terry Pedri ("Petitioner"), filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2018)[2] alleging "a left shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine administered on October 14, 2015." Pet. at 1, ECF No. 1. For the reasons set forth below, I conclude that Petitioner is not entitled to compensation.

I. Procedural History

Petitioner filed her vaccination record, medical records, and an affidavit along with her initial petition. Pet'r's Exs. 1–3, ECF No. 1. This case was originally assigned to the Special Processing Unit ("SPU") for expedited resolution based on the allegations in the petition. ECF No. 5. On July 26, 2018, Petitioner filed her statement of completion. ECF No. 7. Petitioner filed a supplemental affidavit on October 24, 2018. Pet'r's Ex. 4, ECF No. 11-2. A detailed vaccination record was filed on January 11, 2019, along with a second statement of completion. Pet'r's Ex. 5,

[1] Because this Decision contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. *See* 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information the disclosure of which would constitute an unwarranted invasion of privacy. If I, upon review, agree that the identified material fits within this definition, it will be redacted from public access.

[2] Within this decision, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

ECF No. 13-1; ECF No. 14. Petitioner filed additional medical records on June 26, 2019, and an amended statement of completion. Pet'r's Ex. 6, ECF No. 19-2; ECF No. 20.

Respondent filed his Rule 4(c) report on August 26, 2019. Resp't's Report, ECF No. 22. The same day, Respondent filed a motion to reassign the case and argued that, after his "review of the case, complicating factors do exist which suggest that the case should be removed from the SPU." Resp't's Mot. at 1, ECF No. 23. The case was transferred to me on September 17, 2019. ECF Nos. 24–25. On December 5, 2019, Petitioner filed an expert report from Dr. Naveed Natanzi, his curriculum vitae, and medical literature. Pet'r's Exs. 7, 8A–T, ECF No. 27. Respondent filed his responsive expert report from Dr. Geoffrey Abrams, his curriculum vitae, and medical literature on April 10, 2020. Resp't's Exs. A, A1–6, B, ECF No. 29. On May 18, 2020, Petitioner filed a supplemental expert report with medical literature. Pet'r's Exs. 9, 9A–B, ECF No. 30. Respondent filed a supplemental report with medical literature on July 16, 2020. Resp't's Exs. C, C1–C3, ECF No. 31.

On March 18, 2022, the parties indicated a desire to proceed with a ruling on the record. Informal Comm., docketed Mar. 18, 2022. The same day, I ordered Petitioner to file said motion by April 18, 2022. Sched. Order, ECF No. 33. Petitioner filed her motion for a ruling on the record on April 18, 2022. Pet'r's Mot. for Ruling [hereinafter "Pet'r's Mot."], ECF No. 34. Respondent filed his response on May 18, 2022. Resp't's Resp., ECF No. 35. Petitioner did not file a reply.

I am resolving Petitioner's claim on the filed record. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where, in the exercise of their discretion, they conclude that doing so will properly and fairly resolve the case. *See* 42 U.S.C. § 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *Hooker v. Sec'y of Health & Hum. Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided cases on the papers in lieu of hearing and those decisions were upheld). Accordingly, this matter is now ripe for resolution.

II. Factual History

a. Medical Records

Petitioner's pre-vaccination medical history is significant for right leg pain and swelling associated with lower extremity deep venous thrombosis ("DVT")[3] and obesity. Pet'r's Ex. 2 at 1–2, ECF No. 1-5; Pet'r's Ex. 6 at 57, ECF No. 19-2. On October 14, 2015, at age 55, she received a flu vaccine in her left deltoid. Pet'r's Ex. 2 at 6.

Approximately seven weeks post vaccination, on December 4, 2015, Petitioner saw her primary care physician ("PCP"), Dr. Bruce Cohn. *Id.* at 10–11. She reported a "[four] week

[3] Deep venous thrombosis (or deep vein thrombosis) is "thrombosis of one or more deep veins, usually of the lower limb, characterized by swelling, warmth, and erythema[.]" *Dorland's Illustrated Medical Dictionary* 1, 1923 (32nd ed. 2012) [hereinafter "*Dorland's*"]. Thrombosis refers generally to the formation of a "thrombus" or blood clot in the veins that impedes blood flow. *Id.*

'aching' in [her] shoulder [more than in] other joints[.]" *Id.* at 10. She complained that she "[h]ad been awaken [sic] at night due [to] shoulder, back[,] and knees" pain. *Id.* She did not report limitations in movement but stated that she had "pain with changing position at night." *Id.* A physical examination revealed no tenderness to palpation, full range of motion ("ROM"), and no synovitis.[4] *Id.* Dr. Cohn assessed Petitioner with joint pain and prescribed nabumetone.[5] *Id.* at 11.

On January 25, 2016, Petitioner emailed Dr. Cohn complaining that her "[u]pper left arm ache[d] constantly in [the] muscle about where you would receive a shot." *Id.* at 35. She explained that it was "[p]ainful to raise [her] arm over head or [to] bend [her arm] to [the] middle of [her] back – still." *Id.* Petitioner also described right hand stiffness at night and in the morning that improved with flexing exercises. *Id.* She reported additional complaints including pain in her right thigh and hip that self-resolved and pain on the lower left side of her spine. *Id.* She also reported that the previous week, she experienced pain on the upper, right side of her chest, followed by heartburn. *Id.* Lastly, Petitioner reported achy knees and sore wrists. *Id.* She said, "most of this came on mid-Oct[tober]." *Id.*

The next day, on January 26, 2016, Dr. Cohn responded that Petitioner's last exam and lab tests were all normal, which was "obviously good news but d[id] not give [Petitioner and Dr. Cohn] an answer to why [Petitioner] fe[lt] so poorly." *Id.* at 36. Petitioner immediately replied to his email and added that she experienced pain in the lower left side of her spine to the lower right side. *Id.* She continued that after her flu shot, all of her issues started, including bilateral hand pain and right arm pain. *Id.* Petitioner also reported feelings of melancholy beginning "last week[,] as pain [and limited ROM] in [her right] arm [was] not getting better, [and] now [her right] side of [the] middle chest [was] aching and fe[lt] bruised." *Id.* Dr. Cohn responded on January 28, 2016, and asked Petitioner if she had "ever heard of 'fibromyalgia'?"[6] *Id.* at 34. He continued, "[Petitioner's] symptoms may fit with this diagnosis, based on [her] prior normal labs and exam." *Id.*

Petitioner emailed Dr. Cohn the next day, on January 29, 2016, and noted that she was going through menopause. *Id.* She reported that "[t]he night before last[, she] woke up [with three] of [her] toes stiff [with] a burning sensation until [she] worked it out. Yesterday, midday [her right] temple was tender and [] late in the day the whole top – back and around the skull was tender and hurt." *Id.* On January 30, 2016, Dr. Cohn responded and explained that "[w]e can treat this like fibromyalgia" and if Petitioner had fibromyalgia, "there is no[] blood test or x-ray to prove that diagnosis[,and] the best treatment is daily aerobic type exercise." *Id.* He also recommended possible physical therapy ("PT") and daily medication. *Id.* Petitioner responded that she would try aerobic exercise and asked if there are "any foods or diet changes that help or hinder this condition." *Id.* at 35, 51.

On February 6, 2016, Petitioner emailed Dr. Cohn with complaints of "a lot of pain" in the

[4] Synovitis is "inflammation of a synovial membrane; it is usually painful, particularly on motion, and is characterized by a fluctuating swelling due to effusion within a synovial sac." *Dorland's* at 1856.
[5] Nabumetone is "a nonsteroidal anti-inflammatory drug used in the treatment of osteoarthritis and rheumatoid arthritis." *Dorland's* at 1229.
[6] Fibromyalgia is defined as "pain and stiffness in the muscles and joints that either is diffuse or has multiple trigger points." *Dorland's* at 703.

left shoulder area and requested an x-ray. *Id.* at 33. She reported that she had been doing aerobic exercises for the past five days but still had hand stiffness and soreness along with left shoulder and right lower back pain. *Id.* A February 10, 2016 x-ray of Petitioner's left shoulder was normal. *Id.* at 66.

Petitioner presented to Dr. Maika Del Mar, a new PCP, with complaints of joint pain on February 23, 2016. *Id.* at 80–82. Petitioner reported increased pain and limited ROM in her left shoulder, beginning in October of 2015 after a flu shot. *Id.* at 80. She described pain in her right hip, bilateral knee pain, and occasional weakness in her left hand. *Id.* During a physical exam, Petitioner exhibited mild point tenderness in her right hip and lower lumbar and buttocks area with difficulty reaching back and over with her left shoulder. *Id.* at 81. Dr. Del Mar assessed Petitioner with adhesive capsulitis[7] of the left shoulder, lumbar radiculopathy,[8] and "joint pain—fibromyalgia [versus] other, supportive care." *Id.* at 82. Dr. Del Mar recommended PT for Petitioner's fibromyalgia, but Petitioner declined, stating that her "shoulder appear[ed] to be getting better slowly." *Id.* Petitioner's prescription for nabumetone was renewed for her back pain. *Id.* Dr. Del Mar also ordered a lumbar spine x-ray that revealed mild facet arthropathy[9] at L4–L5 and L5–S1. *Id.* at 88.

Between March 10 and May 25, 2016, Petitioner attended four PT appointments. *Id.* at 98–101, 118–29, 145–47. During her initial evaluation on March 10, 2016, Petitioner complained of left shoulder pain when reaching behind and overhead and when lifting baggage overhead on an airplane. *Id.* at 99. She also complained of right hip and low back pain that was aggravated by sitting or driving for more than thirty minutes, bilateral knee pain when standing up and squatting, and left elbow and hand stiffness in the morning. *Id.* The visit record noted in the "mechanism of injury, history and progression" section that "onset [occurred] the day after [she received a] flue [sic] shot [and] started with left shoulder" pain. *Id.* Petitioner's therapist observed shoulder flexion of 170 degrees, external rotation of 50 degrees, and functional internal rotation to L5. *Id.* at 100. Petitioner's elbow and knee movement were within functional limits, but supination was painful in the shoulder, and she experienced internal and external hip rotation stiffness. *Id.*

Following her initial PT visit, on March 13, 2016, Petitioner emailed Dr. Del Mar and requested a cortisone[10] shot in her left shoulder because she could not reach behind her back or pull on a seatbelt "without severe pain." *Id.* at 90. She also reported that nabumetone was no longer working, but she had taken 200mg of ibuprofen the night before and only "woke up once." *Id.* at 91. Petitioner presented to Dr. Del Mar the next day and reported that PT had not helped. *Id.* at 110–12. Dr. Del Mar administered a steroid injection on March 14, 2016. *Id.* at 112.

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[7] Adhesive capsulitis is "adhesive inflammation between the joint capsule and the peripheral articular cartilage of the shoulder with obliteration of the subdeltoid bursa, characterized by shoulder pain of gradual onset, with increasing pain, stiffness, and limitation of motion. Called also *adhesive bursitis* and *frozen shoulder*." *Dorland's* at 286.

[8] Lumbar radiculopathy is a "disease of the lumbar nerve roots, such as from disc herniation or compression by a tumor or bony spur, with lower back pain and often paresthesias." *Dorland's* at 1571.

[9] Arthropathy refers to "any joint disease[,]" generally. *Dorland's* at 158.

[10] Cortisone is "a natural glucocorticoid [a corticosteroid] that is metabolically convertible to cortisol[.]" *Dorland's* at 422.

A PT record dated April 1, 2016, noted that "[a]ll [of Petitioner's] symptoms were resolving." *Id.* at 119. Petitioner reported that her recent cortisone injection had helped. *Id.* On April 22, 2016, Petitioner reported that she was having "very little pain at this time, only with certain positions in the shoulder," and some weakness when playing tennis. *Id.* at 126. A physical exam revealed that Petitioner's ROM was normal, and she reported a return to normal activity with mild symptoms. *Id.* Petitioner attended her last PT session on May 25, 2016. *Id.* at 145–47. She reported very little pain, only with certain hip positions. *Id.* at 146. Petitioner was discharged with a home exercise program after having met her PT goals. *Id.* at 147.

The same day as her last PT session, on May 25, 2016, Petitioner presented to Dr. Del Mar with upper respiratory infection symptoms, and she reported right hip pain. *Id.* at 151. In an email dated June 7, 2016, Petitioner reported to Dr. Del Mar that during her last PT session on May 25, 2016, she utilized "two new additional exercises for the right hip along with the same strengthening exercises for the left shoulder joint where [she] received the original flu shot. All other joints [we]re back to normal." *Id.* at 173.

Petitioner continued to complain of right hip pain throughout 2017. *See, e.g.*, *id.* at 207, 218–19, 225, 234–36. On November 28, 2017, Petitioner was seen by an orthopedist and reported that following her 2015 flu shot, she experienced "multiple joint pain the next day, including the hips." *Id.* at 234. She stated that "[a]ll other joints improved over time except her right hip." *Id.* Petitioner received a steroid injection in her hip and re-entered PT for said hip pain through January of 2018. *See id*. at 234, 241–43, 253–54, 286–87. On March 7, 2018, Petitioner told her gynecologist that "[s]he had a severe systemic reaction with her last flu shot and has not been working since that time but is considering going back now." Pet'r's Ex. 6 at 517.

b. Petitioner's Affidavit

Petitioner described her vaccination and injury in a detailed affidavit filed on October 24, 2018. Pet'r's Ex. 4, ECF No. 11-2.[11] Petitioner stated that "[t]he shot was administered late afternoon, and [she] was standing at the time." *Id*. at 1. Petitioner described the shot as feeling like a "bite, it stung." *Id.* She noted that "[i]mmediately following [her] vaccination, [she] felt pain in [her] left shoulder." *Id*. Petitioner described a "knot at the injection site" and stated that her arm was sore that evening. *Id.* The next day, Petitioner was "extremely sore" and "all [her] joints [were] aching – stiff, inflamed." *Id.* Her symptoms reminded her of a "very bad case of the flu." *Id.* Petitioner stated that she could not move her left arm to reach or pull, because "[i]t was extremely painful and locked up – ached – would[not] move." *Id.* She "felt like [she] turned 90 [years] old overnight." *Id.* She recalled a "total[] los[s of ROM] and [said] it was crazy painful." *Id.* Petitioner stated she was still suffering symptoms after Halloween of 2015 and that she "rested a lot to get over the flu, and was waiting for [her] left shoulder and arm pain to go away." *Id.* at 2. Unable to get comfortable, Petitioner reported that she could not sleep with her "muscles aching." *Id.* She was unable to fasten her seatbelt with her left arm and her shoulder muscles were "screaming and refusing to move." *Id.* Petitioner stated that she was convinced a doctor would tell her "to let this flu vaccine work out of [her] system[,]" so she did not initially seek treatment. *Id.*

[11] Petitioner's first affidavit merely stated the date and location of the vaccination at issue; that her left shoulder pain began "immediately[;]" and the pain persisted for more than six months. *See* Pet'r's Ex. 3, ECF No. 1-6. Its contents will therefore not be discussed in more detail.

After Thanksgiving of 2015, when her "symptoms did not resolve," Petitioner sought medical care. *Id.* She noted her inability to continue with hobbies, including tennis, kayaking, fishing, hiking, and bowling." *Id.*

III. Expert Reports

a. Petitioner's Expert, Naveed M. Natanzi, D.O.

Dr. Natanzi received his undergraduate degree from University of California, Santa Barbara in 2007. Pet'r's Ex. 8A at 2, ECF No. 27-3. He attended Western University of Health Sciences and received his Doctor of Osteopathy degree in 2012. *Id.* From 2013–2016, Dr. Natanzi completed his residency and a fellowship in physical medicine and rehabilitation at the University of California, Irvine. *Id.* Dr. Natanzi worked as an attending physician in interventional medicine and pain management before founding the Regenerative Sports and Spine Institute in 2017. *Id.* at 1. He is board certified by the American Academy of Physical Medicine and Rehabilitation.[12] *Id.* Topics of Dr. Natanzi's publications include vasoactive intestinal peptide tumors and thalamic lacunar infarction. *Id.* He issued two expert reports in the case. *See* Pet'r's Ex. 7; ECF No. 27-2; Pet'r's Ex. 9; ECF No. 30-2.

Dr. Natanzi discussed his qualifications to opine in this matter. He noted his training by Dr. Marko Bodor, "who[, according to Dr. Natanzi,] was the first to describe [SIRVA] in medical literature." Pet'r's Ex. 7 at 1. He also noted that he "almost exclusively treat[s] musculoskeletal issues[,] including but not limited to[,] the shoulder joint." *Id.* Over the previous five years, Dr. Natanzi has provided an expert opinion in "approximately [thirty] medico-legal matters." *Id.* He currently diagnoses and treats forty to fifty shoulder pathologies per month. *Id.*

Following a summary of Petitioner's factual evidence and the medical literature filed in support of his opinions, Dr. Natanzi began his analysis with the temporal relationship between Petitioner's vaccination and pain onset. *Id.* at 7–8. Cautioning that SIRVAs are often believed to be the typical, self-resolving pain associated with vaccinations, he asserted that a patient's delay in seeking treatment is common. *Id.* at 8. Furthermore, the condition is rare and largely unknown to treaters, and Dr. Natanzi opined that the condition is often misdiagnosed. *Id.* at 7. In Petitioner's case, a medical record documenting a visit in mid-December of 2016 placed the onset of Petitioner's shoulder pain four weeks prior, beginning in November of 2016. *Id.* at 8 (citing Pet'r's Ex. 2 at 10). However, Dr. Natanzi characterized this account of pain onset as "a misdocumentation." *Id.* He argued that Petitioner's affidavit and emailed communications with providers establish that Petitioner's pain occurred immediately following vaccination. *Id.* at 7 (citing Pet'r's Ex. 2 at 35, 80; Pet'r's Exs. 3–4). Furthermore, "given the lack of any alternative etiology for the acute development of shoulder pain in the peri-vaccination period," Dr. Natanzi argued that the temporal relationship between Petitioner's vaccine and injury is consistent with a SIRVA. *Id.* at 8.

[12] Dr. Natanzi's curriculum vitae indicates that he is board eligible for certification by the American Board of Pain Management, and there is a "planned for 2018" notation. Pet'r's Ex. 8A at 1. However, his curriculum vitae was filed on December 5, 2019, and it is not clear if this was completed. *See id.*

Dr. Natanzi identified Petitioner's "immediate bite-like sensation," limited ROM the morning after vaccination, and adhesive capsulitis diagnosis as clinical and diagnostic evidence of her SIRVA. *Id.* Petitioner's account that she and the vaccine administrator were standing at the time of her injection, "coupled with the subjective and objective signs of SIRVA," support Dr. Natanzi's opinion of "a strong causal relationship between [Petitioner's October 14, 2015 flu] vaccination and [the onset of her] symptoms." *Id.*

He further explained the "course of events in [Petitioner's] case [that] are consistent with SIRVA." *Id.* at 9. In Dr. Natanzi's opinion, the vaccine administrator "[i]nadvertent[ly] overpenetrat[ed Petitioner's skin with] the vaccination needle resulting in [b]ursal and rotator cuff penetration causing [Petitioner] to experience immediate pain, limited [ROM], and discomfort." *Id.* He continued that meanwhile, the "[v]accine interact[ed] with naturally-occurring antibodies from a prior vaccination [Petitioner received], resulting in an exaggerated, robust, and prolonged inflammatory response[,] resulting in [a]dhesive capsulitis and rotator cuff mediated pain." *Id.* In support, Dr. Natanzi submitted medical literature including an article by Bodor and Montalvo,[13] who Dr. Natanzi claimed "[h]ypothesized that [a vaccine injected into the subdeltoid bursa in two patients caused] a robust inflammatory mediated response." *Id.* at 4 (citing Pet'r's Ex. 8C, ECF No. 27-5). He also submitted an article by Atanasoff et al.,[14] which Dr. Natanzi asserted "[d]escribed that if a vaccine is injected inadvertently into a synovial space (bursa or joint); a prolonged inflammatory response may be initiated." *Id.* (citing Pet'r's Ex. 8J, ECF No. 27-12). Dr. Natanzi noted that his "report is based on many of [Petitioner's] recollections of events, which are presumed to be accurate and were taken at face value." *Id.* at 10.

Dr. Natanzi also discussed Petitioner's possible fibromyalgia diagnosis. *Id.* at 8. According to Dr. Natanzi, Petitioner's "focal and isolated" shoulder pain is inconsistent with Dr. Del Mar's differential fibromyalgia diagnosis because fibromyalgia presents with "diffuse musculoskeletal achiness, stiffness, and tenderness at specific points." *Id.* Other symptoms that are also sometimes seen with fibromyalgia, such as sleep, memory, and mood changes, are also not present in Petitioner's case. *Id.* Dr. Natanzi acknowledged that Petitioner experienced "other peripheral pain conditions" in both of her knees, right hip, and left foot. *Id.* at 9 (citing Pet'r's Ex. 6 at 601; Pet'r's Ex. 2 at 80). He argued that "these complaints are episodic and consistently secondary to the primary complaint of shoulder pain." *Id.* Furthermore, he opined that such symptoms are "completely unrelated to each other, fibromyalgia, or [her] SIRVA injury." *Id.* Dr. Natanzi asserted instead that they "are the result of the typical wear and tear pains that surface in the latter decades of life." *Id.*

In his supplemental expert report, Dr. Natanzi identified potential etiologies for Petitioner's non-shoulder pain. Pet'r's Ex. 9 at 2. He attributed Petitioner's lower back pain to radiculopathy, her left foot pain to tendinitis[15] or a fracture, and her right hip pain to bursitis.[16] *Id.* at 2–3. He also discounted Dr. Del Mar's February 23, 2016 adhesive capsulitis diagnosis because it was not

[13] M. Bodor & E. Montalvo, *Vaccination-related shoulder dysfunction*, 25 VACCINE 585–87 (2007).
[14] S. Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 VACCINE 8049–52 (2010).
[15] Tendinitis is "inflammation of tendons and of tendon-muscle attachments[.]" *Dorland's* at 1881.
[16] Bursitis is "inflammation of a bursa, occasionally accompanied by a calcific deposit in the underlying tendon; the most common site is the subdeltoid bursa." *Dorland's* at 264.

supported by a "documented physical exam." *Id.* at 2. Rather, Petitioner's PT notes show she had "grossly preserved flexion and significant limitation in internal rotation." *Id.* (citing Pet'r's Ex. 2 at 100, 120). He then noted the Saleh et al.[17] article that "described a case of SIRVA-mediated capsulitis in a 30-year-old with preserved flexion and limited external and internal rotation." *Id.* (citing Pet'r's Ex. 9B at 2, ECF No. 30-4). The study, according to Dr. Natanzi, revealed "findings [that] almost identically mimic" those in Petitioner's PT notes, if her arm was tested from the abducted position. *Id.* Saleh et al. defined adhesive capsulitis as a "diagnosis of exclusion[, meaning] other diagnoses need to be ruled out." Pet'r's Ex. 9B at 4. Patients within the study had negative radiological findings and had ruled out other possible causes, such as rotator cuff tears, tendonitis, and bursitis. *Id.*

Dr. Natanzi also discussed why patients may not seek medical care right after suffering an injury. Pet'r's Ex. 9 at 1. He filed an article by Taber et al.[18] that "present[ed] a comprehensive description and conceptual categorization of reasons people avoid medical care." Pet'r's Ex. 9A at 1, ECF No. 30-3. The study identified three main categories: 1) unfavorable evaluations; 2) low perceived need for care; and 3) traditional barriers to care. *Id.* at 6. Dr. Natanzi asserted that Petitioner's belief that her condition would self-improve over time is a common example of a low perceived need to seek care. Pet'r's Ex. 9 at 4 (citing Pet'r's Ex. 4; Pet'r's Ex. 9A at 5). Despite Petitioner's delay in seeking care, her specific descriptions of the pain immediately post vaccination and the morning after "suggests [to Dr. Natanzi,] a clear temporal relationship between vaccination and the onset of her symptoms." *Id.* at 1.

b. Respondent's Expert, Geoffrey D. Abrams, M.D.

Dr. Abrams received his undergraduate degree from Stanford University and his medical degree from University of California, San Diego. Resp't's Ex. B at 1, ECF No. 29-8. He completed his internship and residency at Stanford University School of Medicine in the departments of general surgery and orthopedic surgery, respectively. *Id.* Since 2013, Dr. Abrams has been employed as an assistant professor at Stanford University School of Medicine and as an attending physician at the Veterans Administration Hospital in Palo Alto. *Id.* He is also currently the director of the Lacob Family Sports Medicine Center at Stanford and "serve[s] as the [t]eam [p]hysician for numerous professional and collegiate sports teams in the San Francisco Bay Area." Resp't's Ex. A at 1, ECF No. 29-1. Dr. Abrams is board certified in orthopedic surgery with a subspecialty in orthopedic sports medicine. Resp't's Ex. B at 2. He has published articles on rotator cuff injuries, arthroscopy, and synovial inflammation. *Id.* at 2–8. He issued two expert reports in this case. *See* Resp't's Ex. A; Resp't's Ex. C, ECF No. 31-1.

He began by arguing Petitioner did not suffer from a SIRVA. Resp't's Ex. A at 4. Petitioner's failure to seek medical care immediately post vaccination is the first indicator for Dr. Abrams that the onset for her shoulder pain was "well outside the 48-hour window typically seen for consideration of a SIRVA diagnosis." *Id.* Furthermore, Dr. Abrams asserted that in SIRVA cases, "pain and reduced [ROM] should be limited to the shoulder in which the vaccine was

[17] Z. Saleh et al., *Onset of Frozen Shoulder Following Pneumococcal and Influenza Vaccinations,* 14 J. CHIRO. MED. 285–89 (2015).
[18] J. Taber et al., *Why do People Avoid Medical Care? A Qualitative Study Using National Data,* 30(3) J. GEN. INT. MED. 290–97 (2015).

administered." *Id.* at 5. However, Petitioner had "numerous musculoskeletal complaints in the months following the injection." *Id.* He noted simultaneous complaints of aching in Petitioner's shoulder, back, and knees during her initial visit with her PCP, seven weeks post vaccination. *Id.* (citing Pet'r's Ex. 2 at 10). He also noted Petitioner's complaints in January of 2016, three months post vaccination, of "right hand stiffness, right thigh into hip pain, lower left of spine upper hip soreness (later corrected to the right side), right upper chest pain, achy knees, and wrist soreness." *Id.* (citing Pet'r's Ex. 2 at 36–37).

In light of these complaints, Dr. Abrams agreed with Dr. Del Mar's fibromyalgia assessment. *Id.* at 6. He used The American College of Rheumatology's ("ACR") classification criteria to evaluate Petitioner's presentation and reach his conclusion. *Id.* (citing Resp't's Ex. A3, ECF No. 29-4).[19] The ACR "develop[ed] simple, practical criteria for [the] clinical diagnosis of fibromyalgia that are suitable for use in primary and specialty care." Resp't's Ex. A3 at 10. The patient must have a widespread pain index ("WPI") of 7 or greater and a symptom severity ("SS") scale score greater than 5. Resp't's Ex. A at 6. Symptoms must be present for at least three months, and the patient cannot have a disorder that would otherwise explain the pain. *Id.* at 7.

Dr. Abrams determined that Petitioner would have a WPI of 10, based on her description of pain in ten of nineteen possible locations on the body.[20] *Id.* at 6. Dr. Abrams calculated Petitioner's total SS score at 5–8. *Id.* at 7. He broke the SS total down into three components: fatigue, waking un-refreshed, and cognitive symptoms. *Id.* According to the classification system, 1 indicates slight or mild, intermittent problems; 2 indicates moderate, considerate problems; and 3 indicates severe and continuous, life-disturbing problems. *Id.* at 7. First, he assigned Petitioner a score of 2–3 for fatigue due to her reports of waking up at night from hand and foot pain. *Id.* (citing Pet'r's Ex. 2 at 2–3). Dr. Abrams also assigned Petitioner a score of 2–3 for waking un-refreshed, due to the same reports. *Id.* Lastly, Petitioner reported feeling melancholy, which Dr. Abrams recorded as a cognitive symptom, and he assigned a severity score of 1–2. *Id.* (citing Pet'r's Ex. 2 at 36). Dr. Abrams argued that at a minimum, Petitioner would have a SS scale score of 5. *Id.*

He noted that Petitioner's symptoms had been present "at a similar level" for at least three months, therefore satisfying the ACR's three-month severity requirement for a fibromyalgia diagnosis. *Id.* Citing the medical record, Dr. Abrams argued that Petitioner's fibromyalgia symptoms "began [four] weeks prior to her visit with Dr. Cohn on December 4, 2015," or during October of 2015, immediately post vaccination. *Id.* (citing Pet'r's Ex. 2 at 10, 80). Dr. Abrams wrote that this therefore places the duration of symptoms "from approximately late October/early November until at least late January – the time of the emails – a time period of [three] months." *Id.* (citing Pet'r's Ex. 2 at 34–36). Lastly, Dr. Abrams noted that he and Petitioner's expert agree, "no other objective medical conditions would explain the multiple musculoskeletal complaints of [P]etitioner at th[at] time." *Id.* at 7–8. He opined that Petitioner's clinical presentation is consistent with fibromyalgia, and she did not suffer from SIRVA. *Id.* at 8.

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[19] F. Wolfe et al., *The American College of Rheumatology Preliminary Diagnostic Criteria for Fibromyalgia and Measurement of Symptom Severity*, 62(5) ARTHR. CARE & RES. 600–10 (2010).

[20] Petitioner reported pain in her left shoulder girdle, left lower arm/wrist, right lower arm/hand/wrist, right hip, upper right leg/thigh, lower right leg/knee, toes, lower left leg/knee/toes, right jaw/temple, and right upper chest. Resp't's Ex. A at 6 (citing Pet'r's Ex. 2 at 35–37).

In support of his argument that Petitioner did not have SIRVA, Dr. Abrams filed articles to rebut Dr. Natanzi's opinion that Petitioner suffered from "SIRVA [m]ediated [c]apsulitis." *See* Resp't's Exs. C2–C3, ECF Nos. 31-3–31-4.[21] The Erickson et al. article noted that adhesive capsulitis patients, "depending on the stage of the disease process at presentation, may present with pain, pain and loss of motion, or loss of motion with minimal pain." Resp't's Ex. C2 at 1. The inclusion criteria for the study included "active and passive restriction of ROM of 20 [degrees] or more in any plane compared with the contralateral shoulder." *Id.* Patients in the study with adhesive capsulitis "had average forward flexion of the shoulder of 114 [+/-33] degrees (and external rotation of 29 [+/-14] degrees with the arm at the side." *Id.* at 2. The Rundquist et al. article analyzed frozen shoulder "characterized by the spontaneous onset of pain in the shoulder with restriction of movement in every direction." Resp't's Ex. C3 at 1. The authors identified adhesive capsulitis as a subset of frozen shoulder. *Id.* They noted that "[q]uantifying the ROM diagnostic of frozen shoulder has not been consistent," and "[m]aximal abduction and maximal external rotation reported vary considerably." *Id.* Rundquist et al.'s "[i]nclusion criteria for the study required subjects to have a maximum elevation angle relative to the trunk of less than 120 [degrees]." *Id.* at 4. The Rundquist et al. article noted "average flexion of 117 degrees" (and external rotation of 35 degrees with the arm abducted). Resp't's Ex. C at 2. Both averages are "well below [P]etitioner's documented range" of 170 degrees of shoulder flexion and 50 degrees of external rotation. *Id.* at 3. Dr. Abrams also noted that an MRI was not done in Petitioner's case. Resp't's Ex. A at 8. Without an MRI, "[t]here is no objective evidence of SIRVA in this case." *Id.*

He then disputed Dr. Natanzi's description of the course of events and his theory that overpenetration of the needle into Petitioner's shoulder resulted in a SIRVA. *Id.* Dr. Abrams argued that, despite the assertions Dr. Natanzi used to support his theory, there is no objective evidence of the injection location (high versus low), the position of Petitioner's arm at the time of vaccination, or the posture of Petitioner and the administrator during vaccination. *Id.* Petitioner's recount "given during an affidavit nearly three years after the injection in question," is not reliable in Dr. Abrams' opinion. *Id.* He questioned the reliability of Petitioner's memory and, in support, filed articles on the accuracy of memory recall. Resp't's Exs. A1–A2, ECF Nos. 29-2–29-3.[22]

Finally, Dr. Abrams argued that Petitioner's higher-than-average body mass index ("BMI") made it unlikely that the needle could have reached her subacromial space. Resp't's Ex. A at 9. He filed the Nakajima et al.[23] article, which endeavored "to identify a safer intramuscular ("IM") injection site in the deltoid muscle because of possible complications following the vaccine administration of IM injections." Resp't's Ex. A4, ECF No. 29-5. As part of their foundational research, the authors identified the thickness of skin and muscle in "a limited number of [healthy] subjects in terms of [BMI,] as well as the small sample size and age." *Id.* at 5. They used these

[21] B. Erickson et al., *Adhesive Capsulitis: Demographics and Predictive Factors for Success Following Steroid Injections and Surgical Intervention*, 1(1) ARTHROP, SPORTS MED. & REHABIL. 35–40 (2019); P. Rundquist, et al., *Shoulder Kinematics in Subjects with Frozen Shoulder*, 84 ARCH. PHYS. MED. REHABIL. 1473–81 (2003).

[22] J. Lacy, et al., *The Neuroscience of Memory: Implications for the Courtroom*, 14(9) NAT. REV. NEUROSCI. 649–58 (2013); E. Loftus, *Planting misinformation in the human mind: A 30-year investigation of the malleability of memory*, 12 LEARNING & MEMORY 361–66 (2005).

[23] Y. Nakajima et al., *Establishing a new appropriate intramuscular injection site in the deltoid muscle*, 13(9) HUM. VACC. & IMMUNOTHER. 2123–29 (2017).

numbers as a basis to calculate the "appropriate depth and angle of needle insertion" to minimize injury due to overpenetration. *Id.* The authors cautioned that while they "guess [their newly proposed injection site] is also applicable to obese subjects[, they] do not have any data on the location of axillary nerve, [posterior circumflex humeral artery ("PCHA")] and subcutaneous thickness, [and] further studies are required to identify safer sites for IM injection in obese subjects." *Id.* Based on the Nakajima et al. article, Dr. Abrams opined that "the needle would have to transverse a distance (skin plus deltoid thickness) of up to approximately 28 mm in order to minimally reach the bursa. The rotator cuff would be even further." Resp't's Ex. A at 9. Based on Petitioner's weight, Dr. Abrams estimated that the standard needle for a flu vaccination for her would be 25.4 mm. *Id.* He asserted that "over penetration is more likely in patients with lower BMI," unlike in Petitioner's case. *Id.* (citing Pet'r's Ex. 8M at 5, ECF No. 27-15).[24] He concluded that the needle length, the target distance, and Petitioner's anatomy do not support Dr. Natanzi's contention that over penetration occurred. *Id.*

IV. Ruling on the Record

a. Petitioner's Motion

Petitioner maintained in her motion for a ruling on the record "that she has suffered a 'Table' injury through her satisfaction of the Qualifications and Aids to Interpretation [("QAIs")] criteria for SIRVA." Pet'r's Mot. at 8. She asserted that Respondent does not dispute that Petitioner had no medical history indicative of "pain, inflammation, or dysfunction of the affected shoulder prior to intramuscular vaccine administration." *Id.* Petitioner also stated that Respondent did not contest her assertion "that no other condition or abnormality is present that would explain [her] symptoms." *Id.* Petitioner focused her argument on the remaining two Table SIRVA criteria: 1) symptoms occurring within forty-eight hours of vaccination and 2) injury limited to the shoulder of vaccination. *Id.*

Regarding the onset of her symptoms, Petitioner relied on her affidavit wherein she described pain that occurred "immediately" post vaccination. *Id.* (citing Pet'r's Ex. 4 at 1). Petitioner referred to this recounting, the multiple instances in which she related her pain to vaccination in communications with her medical providers, and her recount of the sore knot at the injection site as evidence that is "strongly supportive of forty-eight (48) hour onset." *Id.* Although Petitioner acknowledged that she suffered from pain in areas other than her shoulder, including her back, knees, hands, and hip, she argued that the QAIs "cannot be read so strictly as to require a [p]etitioner to be free of any and all painful ailments at the time of vaccination in order to establish a Table injury." *Id.* at 9. Petitioner continued that "she sought treatment for her shoulder more consistently and more often" than for pain in any other area. *Id.* She also maintained that her shoulder pain occurred first. *Id.* She contended that her complaints of "peripheral pain were unrelated to each other, unrelated to any potential diagnosis of fibromyalgia, and unrelated to [her] SIRVA." *Id.* As additional support, Petitioner noted that her expert characterized her peripheral pain as "episodic and consistently secondary." *Id.*

[24] G. Okur et al., *Magnetic resonance imaging of abnormal shoulder pain following influenza vaccination*, 43 SKELETAL RADIOL. 1325–31 (2014).

Table claim notwithstanding, Petitioner submitted arguments in support of a but-for causation claim. *Id.* at 9–12. She first asserted that "*Althen* prong one is not at issue." *Id.* at 9. She continued that due to "extensive medical literature causally relating shoulder injuries to vaccinations," her causation theory "regarding shoulder injuries has become well established." *Id.* at 9–10. According to Petitioner, Dr. Natanzi explained this mechanism as an "inadvertent overpenetration of the vaccination needle," that is accompanied by the chemical interaction of the vaccine "with naturally-occurring antibodies from prior vaccinations." *Id.* at 10. This led "to an exaggerated and prolonged inflammatory response" in Petitioner. *Id.*

To satisfy *Althen* prong two's requirement to present a logical sequence of cause and effect, Petitioner argued that "the entirety of [her] treatment course, when viewed together with her testimony, support a development of left shoulder symptoms immediately following vaccination." *Id.* at 11. She acknowledged that she "experienc[ed] a plethora of symptoms throughout her treatment course, and the records most contemporaneous to the vaccination, viewed alone, are unclear as to when each symptom began." *Id.* at 10. However, she stated that "in her message to Dr. Cohn on January 26, 2016, [she] seemed to clarify her onset, noting that she 'got a flu shot [and] all this started." *Id.* at 11. Petitioner continued that her later complaints "all refer back to the flu vaccination as the event that spurred onset of her symptoms." *Id.* (citing Pet'r's Ex. 2 at 44, 80, 98, 110).

Finally, Petitioner noted that "it is not a requirement that a petitioner specify the date of vaccination when reporting onset of pain to a provider or third-party, nor is it a requirement that a petitioner accurately recall the month or day of their vaccination." *Id.* at 11–12 (citing *Williams v. Sec'y of Health & Hum. Servs.*, No. 17-1046V, 2020 WL 3579763, at *5 (Fed. Cl. Spec. Mstr. Apr. 1, 2020)). She reiterated that "[e]ven if [her] complaints at her first [doctor's] visit [post vaccination] are read to place onset of her shoulder pain three weeks post vaccination, this particular record is heavily outweighed by [her] testimony." *Id.* at 12.

b. Respondent's Response

Respondent relied heavily on Petitioner's December 4, 2015 medical exam record to place "onset [of her symptoms at] approximately three weeks after vaccination." Resp't's Resp. at 10. Furthermore, Respondent argued that at that time, Petitioner did not specifically "attribute her shoulder pain (or other complaints) to the flu vaccine." *Id.* at 11 (citing Pet'r's Ex. 2 at 35). Respondent continued that in February, four months post vaccination, "[P]etitioner presented to her new PCP and reported left shoulder pain 'after' a flu shot but did not specify when after the vaccine her pain began." *Id.* (citing Pet'r's Ex. 2 at 80–82). Ultimately, "Petitioner's claims in her affidavits that the onset of her pain was immediate and persisted thereafter are not corroborated by the contemporaneous medical records, were created years after the events in question, and amount to her word alone." *Id.*

In response to Petitioner's assertion that delayed reporting is common, Respondent contended that in Petitioner's case, a delay in seeking treatment is "difficult to fathom." *Id.* As support for this opinion, Respondent cited Petitioner's claims that "she could not reach over her head or back to dress herself, she could not buckle her seatbelt or sleep on her left side, she felt like she 'turned 90 years old overnight,' her left arm ached severely just to move it, and it was

crazy painful." *Id.* at 11–12. Despite these extreme symptoms, Petitioner "waited seven weeks to seek medical care because she 'thought it was just going to work itself out.'" *Id.* at 12 (citing Pet'r's Ex. 4 at 2). Respondent argued that the severity and scope of Petitioner's described symptoms undercut this claim, and therefore, "[P]etitioner has not established by preponderant evidence that the onset of her left shoulder pain occurred within forty-eight hours of her October 14, 2015 vaccination." *Id.*

In direct disagreement with Petitioner, Respondent argued that "the medical records establish that from her first complaint, [P]etitioner described back, knee, hand, and hip pain, beginning in the same time frame" as her purported shoulder pain. *Id.* Respondent continued that Petitioner's medical records refute her arguments "that her other musculoskeletal complaints were 'episodic,' 'consistently secondary' to her shoulder pain, and that 'the onset of these other conditions is unclear.'" *Id.* (citing Pet'r's Mot. at 9). He quoted Petitioner's affidavit stating that "she woke up the next morning after her vaccination with all of her joints aching – stiff, inflamed – extremely sore." *Id.* (citing Pet'r's Ex. 4 at 1). Her report of "multiple musculoskeletal complaints beginning in the same time frame," precludes a Table claim because "the language of the QAI specifies that pain outside the shoulder in which the vaccine was administered is [a] sufficient" disqualifier. *Id.* at 13.

Consistent with Respondent's argument that Petitioner's pain was not limited to her shoulder, Respondent further argued that Petitioner cannot successfully assert a Table claim because fibromyalgia is another "condition or abnormality [] present that would explain her symptoms." *Id.* As support, Respondent reiterated Dr. Abrams' point that Petitioner "meets the [ACR] criteria for fibromyalgia, a diagnosis also raised by her treating medical providers." *Id.* Additionally, Dr. Abrams also noted that "[P]etitioner never had an MRI, so there is no imaging to support her alleged SIRVA." *Id.* at 14.

Regarding Petitioner's off-Table claim, Respondent cited the legislative history that is discussed in *Grant v. Sec'y of Health & Hum. Servs.*, wherein the Federal Circuit noted that in off-Table cases, "[s]imple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation[.]" *Id.* at 15 (citing *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144 (Fed. Cir. 1992)). The Circuit continued, "evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a petitioner." *See id.* Respondent contended that Petitioner has not identified "a medically recognized injury" for a medical causation theory to be applicable. *Id.* at 16. Petitioner relied on limited ROM to support her SIRVA claim. *Id.* However, Respondent argued that a non-specific injury "to the bursa, ligaments, and tendons of the shoulder" is not a diagnosis. *Id.* He further noted Dr. Abrams' assertion that Dr. Natanzi's adhesive capsulitis diagnosis is inconsistent with Petitioner's "normal shoulder flexion to 170 degrees and external rotation to 50 degrees." *Id.*

Pursuant to *Althen*, Petitioner must establish "a medical theory causally connecting vaccination and the injury." *Id.* (citing *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)). In tandem with Respondent's contention that Petitioner has not established a specific diagnosis, he further argued "Petitioner has not set forth a reliable medical theory" of causation. *Id.* at 17. Respondent summarized Petitioner's theory as "over penetration of the needle into the deep structures of the shoulder." *Id.* He acknowledged that "medical literature supports

that vaccination can be associated with shoulder injuries," but he argued that the case studies filed do "not provide preponderant evidence of a mechanism for *how* vaccinations can cause shoulder injuries." *Id.* at 17–18 (emphasis in original). Respondent then discounted the mechanism mentioned in the articles Petitioner filed. *Id.* at 18. Specifically, he contended that while a prolonged inflammatory response following an inadvertent injection into the shoulder joint is plausible, plausibility is not the standard. *Id.*

Every aspect of Petitioner's claim is disputed by Respondent. *See generally id.* Respondent asserted that Petitioner's injury is not consistent with SIRVA and that unrelated, contemporaneous complaints of pain in other areas preclude a Table claim. *Id.* at 20–21. Furthermore, Respondent argued that Petitioner did not present preponderant evidence of a general causation theory, nor did she provide preponderant evidence that her causation theory is consistent with the facts in her case. *Id.* Respondent requested dismissal of Petitioner's claim. *Id.* at 21.

V. Applicable Statutory Scheme

The Vaccine Act provides petitioners with two avenues to receive compensation for their injuries resulting from vaccines or their administration. First, a petitioner may demonstrate that she suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the provided time period. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); § 13(a)(1)(B).

The Vaccine Injury Table lists a Shoulder Injury Related to Vaccine Administration or "SIRVA" as a compensable injury if it occurs within 48 hours of administration of a vaccination. § 300aa-14(a) as amended by 42 C.F.R. § 100.3. Table Injury cases are guided by statutory QAIs, which provide more detailed explanation of what should be considered when determining whether a petitioner has actually suffered an injury listed on the Vaccine Injury Table. 42 C.F.R. § 100.3(c). To be considered a "Table SIRVA," a petitioner must show that her injury fits within the following definition:

> SIRVA manifests as shoulder pain and limited [ROM] occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g., tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis . . . . A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time-frame;

(iii) Pain and reduced [ROM] are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. §100.3(c)(10).

Alternatively, if a petitioner is unable to establish a Table claim, she may bring an "off-Table" claim. § 11(c)(1)(C)(ii). An "off-Table" or cause-in-fact claim requires that the petitioner "prove by a preponderance of the evidence that the vaccine at issue caused the injury." *Capizzano*, 440 F.3d at 1320; *see* 42 U.S.C. § 300aa-13(a)(1)(A); *see* § 11(c)(1)(C)(ii)(II). A petitioner must show that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006) (citations omitted).

In the seminal case of *Althen v. Sec'y of the Dept. of Health & Hum. Servs*., the Federal Circuit set forth a three-pronged test used to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. *See* 418 F.3d at 1278–79. The *Althen* test requires petitioners to set forth: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278. To establish entitlement to compensation under the Program, a petitioner is required to establish each of the three prongs of *Althen* by a preponderance of the evidence. *See id.*

Under the first prong of *Althen*, a petitioner must offer a scientific or medical theory that answers in the affirmative the question: "can the vaccine[] at issue cause the type of injury alleged?" *See Pafford v. Sec'y of Health & Hum. Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *mot. for rev. denied*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Knudsen*, 35 F.3d at 548–49. Petitioners are not required to identify "specific biological mechanisms" to establish causation, nor are they required to present "epidemiologic studies, rechallenge[] the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities." *Capizzano*, 440 F.3d at 1325 (quoting *Althen*, 418 F.3d at 1280). Scientific and "objective confirmation" of the medical theory with additional medical documentation is also unnecessary. *Althen*, 418 F.3d at 1278–81; *Moberly*, 592 F.3d at 1322. However, as the Federal Circuit has made clear, "simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) (citing *Moberly*, 592 F.3d at 1322). Rather, "[a] petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case." *Moberly*, 592 F.3d at 1322. In general, "the statutory standard of preponderance of the evidence requires a petitioner to demonstrate that the vaccine more likely than not caused the condition alleged." *LaLonde*, 746 F.3d at 1339.

Under the second prong of *Althen*, a petitioner must prove that the vaccine actually did cause the alleged injury in a particular case. *See* 418 F.3d at 1279. The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Id.* at 1278; *Capizzano*, 440 F.3d at 1326; *Grant*, 956 F.2d at 1148. A petitioner does not meet this obligation by showing only a temporal association between the vaccination and the injury; instead, the petitioner "must explain *how* and *why* the injury occurred." *Pafford*, 2004 WL 1717359, at *4 (emphasis in original). The special master in *Pafford* noted petitioners "must prove [] both that [the] vaccinations were a substantial factor in causing the illness . . . and that the harm would not have occurred in the absence of the vaccination." *See* 2004 WL 1717359, at *4 (citing *Shyface*, 165 F.3d at 1352). A reputable medical or scientific explanation must support this logical sequence of cause and effect. *Hodges v. Sec'y of Health & Hum. Servs.*, 9 F.3d 958, 961 (Fed Cir. 1993) (citation omitted). Nevertheless, "[r]equiring epidemiologic studies . . . or general acceptance in the scientific or medical communities . . . impermissibly raises a claimant's burden under the Vaccine Act and hinders the system created by Congress . . . ." *Capizzano*, 440 F.3d at 1325–26. "[C]lose calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280.

In Program cases, contemporaneous medical records and the opinions of treating physicians are favored. *Capizzano*, 440 F.3d at 1326 (citing *Althen*, 418 F.3d at 1280). Indeed, when reviewing the record, a special master must consider the opinions of treating physicians. *Id.* This is because "treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Id.* In addition, "[m]edical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). While a special master must consider these opinions and records, they are not "binding on the special master or court." 42 U.S.C. § 300aa-13(b)(1). Rather, when "evaluating the weight to be afforded to any such . . . [evidence], the special master . . . shall consider the entire record . . . ." *Id.*

To satisfy the third *Althen* prong, a petitioner must establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id.* However, "cases in which onset is too soon" also fail this prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id.*; *see also Locane v. Sec'y of Health & Hum. Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

Although a temporal association alone is insufficient to establish causation, under the third prong of *Althen*, a petitioner must show that the timing of the injury fits with the causal theory. *See Althen*, 418 F.3d at 1278. The special master cannot infer causation from temporal proximity alone. *See Thibaudeau v. Sec'y of Health & Hum. Servs.*, 24 Cl. Ct. 400, 403–04 (1991); *see also Grant*, 956 F.2d at 1148 ("[T]he inoculation is not the cause of every event that occurs within the ten[-]day period . . . [w]ithout more, this proximate temporal relationship will not support a finding of causation." (quoting *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983))).

Once a petitioner has established her *prima facie* case, the burden then shifts to Respondent to prove, also by preponderant evidence, that the alleged injury was caused by a factor unrelated to vaccination. *Althen*, 418 F.3d at 1278 (citations omitted); § 300aa-13(a)(1)(B). The Vaccine Act requires Respondent to establish that the factor unrelated to the vaccination is the more likely or principal cause of the injury alleged. *Deribeaux v. Sec'y of Health & Hum. Servs.*, 717 F.3d 1363, 1369 (Fed. Cir. 2013). Such a showing establishes that the factor unrelated, not the vaccination, was "principally responsible" for the injury. *See* § 300aa-13(a)(2)(B). The factor unrelated must be the "sole substantial factor[;]" therefore, Respondent must establish that the factor unrelated, not the vaccination, actually caused the injury alleged. *See de Bazan*, 539 F.3d at 1354.

VI. Discussion

In the present case, the parties are unable to agree on any material fact or legal conclusion, save that Petitioner's flu vaccination occurred on October 14, 2015. Petitioner maintains that she suffered a left-sided shoulder injury that satisfies the QAI criteria for a SIRVA. Pet'r's Mot. at 8. Alternatively, Petitioner asserts that she "can demonstrate entitlement on a cause-in-fact theory." *Id.* at 9. Respondent, however, disputes the characterization of the claim as on-Table, the timing of onset, the nature of Petitioner's symptoms, and the diagnosis. *See generally* Resp't's Resp. Respondent also argues that Petitioner has not presented preponderant evidence of general or specific causation to satisfy an off-Table claim. *Id.* After a thorough review of the record, I find that Petitioner has not presented preponderant evidence of a Table claim. Additionally, Petitioner has submitted evidence in support of a theory of causation, a logical sequence of cause and effect, and an appropriate temporal relationship. However, Petitioner has not presented preponderant evidence that she suffered from an off-Table shoulder injury caused by vaccination. [25]

a. Table Claim

i. No History of Pain, Inflammation, or Dysfunction

Respondent as much as conceded that Petitioner's claim satisfies the first of the four QAI factors for a Table SIRVA, that Petitioner did not suffer from prior pain, inflammation, or dysfunction of the shoulder. In Petitioner's motion for a ruling on the record, she noted the absence of history of pain, inflammation, or dysfunction of her left shoulder that would explain her post-vaccination injuries. While Petitioner has therefore satisfied the first QAI criterion, Petitioner must

[25] All shoulder injuries that are alleged to have been caused by a vaccine are by definition *related to vaccine administration*. In order to distinguish between the Table defined SIRVA and all other vaccine-caused shoulder injuries that do not fit within the parameters for the Table presumption, I refer to the shoulder injuries alleged as part of a causation-in-fact claim as off-Table shoulder injuries caused by vaccination.

still establish that her pain onset occurred within the specified timeframe, that her injury was localized to her shoulder, and a lack of an alternative condition to explain her symptoms.

ii. 48-Hour Symptom Onset

A review of Petitioner's medical record does not provide a clear or consistent account of her shoulder pain onset. Petitioner's first post-vaccination doctor's visit occurred on December 4, 2015, approximately seven weeks after her injection. At that time, she reported a four-week aching in her left shoulder and other joints. Pet'r's Ex. 2 at 10–11. That would place symptom onset relevant to SIRVA in early November of 2015, more than two weeks after her October 14, 2015 vaccination. In an email dated January 25, 2016, Petitioner complained to Dr. Cohn of pain in her left arm "about where you would receive a shot."[26] *Id.* at 35. She also stated that her pain began in mid-October. *Id.* This account is more consistent with Petitioner's later assertion in her affidavits, authored in 2018, that her pain began immediately after vaccination. *See* Pet'r's Exs. 3–4. Petitioner did not mention any belief that the vaccine and her symptoms were related in her January 25, 2016 email to Dr. Cohn, but in a follow-up the next day, she stated that all of her symptoms started after her flu shot. Pet'r's Ex. 2 at 36. These symptoms included bilateral hand pain and right arm pain. *Id.* Even in these excerpted communications, Petitioner did not indicate if her symptoms began immediately after her injection, later the same day, or in the following days. Petitioner eventually saw a new PCP on February 23, 2016, and described left shoulder pain and limited ROM after her flu shot in October of 2015. *Id.* at 80–82. This is her first account of a clinical presentation that is consistent with a Table SIRVA in scope of injury, timeframe, and with a direct reference to her vaccination. Although Petitioner initially described symptoms beginning in November of 2015, thereafter, she consistently referred to the flu shot as a landmark for the onset of her pain.

For instance, in her detailed affidavit authored in October of 2018, Petitioner described a previously unreported knot at the injection site, accompanied by pain immediately post vaccination and soreness later in the day. Pet'r's Ex. 4 at 1. These symptoms were not reported to any of her treaters at any time post vaccination. Petitioner also noted that she had a "total" loss of ROM and that she was unable to sleep or participate in any hobbies. *See id.* at 1–2. Again, she did not report this to her treaters. I do not find it more likely than not that Petitioner's presentation as described in her October 2018 affidavit is more credible than her contemporaneous reports to her PCP made closer in time to the date of her vaccination. It is true that Petitioner consistently stated that her pain began post vaccination, but she did not specify if the onset of that pain was in the hours or days immediately thereafter. Furthermore, if during her initial complaint to treaters on December 4, 2015, she misremembered the specific onset date, it is unlikely she would also have forgotten pain and a knot that occurred in the few hours or days immediately following vaccination. Based on the above, I do not find preponderant evidence that Petitioner experienced shoulder pain within 48 hours of vaccination. As Petitioner cannot satisfy the second QAI criterion, she cannot establish a Table SIRVA. However, for the sake of completeness, I will discuss the remaining QAI criteria.

iii. Nature of Symptoms

[26] Petitioner's description of her arm pain, without an association to her actual October 14, 2015 vaccination, could merely be a reference to location.

Petitioner conceded that she had contemporaneous pain in areas other than her shoulder post vaccination but argued that the QAI should not be read so strictly as to preclude "any and all painful ailments at that time of vaccination." Pet'r's Mot. at 8. However, the QAI factor that informs this analysis is succinct. For Petitioner's Table SIRVA claim to be successful, she must submit preponderant evidence that her "pain and reduced [ROM] are limited to the shoulder in which the intramuscular vaccine was administered." 42 C.F.R. §100.3(c)(10). Petitioner is correct that the QAI does not preclude any and all ailments. For example, it is possible that someone who went on a hike the day after a vaccination and suffered a minor fall and an ankle fracture could also have a viable, unrelated SIRVA claim. The defining factor in that hypothetical is the ability to separate and account for the vaccine-related shoulder pain in onset and scope. In the hypothetical, the petitioner's SIRVA would, presumably, have manifested in the hours or day after vaccination, and the ankle fracture would have caused immediate pain following the fall. The hypothetical petitioner would therefore be able to differentiate the pain in terms of onset and scope.

In Petitioner's case, she associated all of her ailments, including her shoulder pain, with a common manifestation period and cause. Despite her expert's assertion that her peripheral pain was "episodic" and "unrelated to [her] SIRVA," her medical records do not support that such pain should be separately considered. For example, her initial December 4, 2015 complaint described aching and pain in her back and knees, and an exam revealed no ROM loss. Pet'r's Ex. 2 at 11. The following January, Petitioner complained that her "[u]pper left arm ache[d] constantly in [the] muscle about where you would receive a shot" and that she had hand stiffness, right thigh and hip pain, achy knees, and sore wrists. *Id.* at 35. Petitioner continued to complain of left shoulder pain through early February of 2016, but she also reported hand stiffness and lower right back pain. *Id.* at 33. After changing to a different PCP in late February, she specified that her left shoulder pain and limited ROM began in October post vaccination, but she also complained of right hip pain, bilateral knee pain, and left-hand weakness. *Id.* at 80. In March of 2016, Petitioner complained of left shoulder pain, right hip and low back pain, bilateral knee pain, and left elbow and hand stiffness. *Id.* at 98–101. PT records also suggest that Petitioner considered her multiple ailments related. An April 1, 2016 record included Petitioner's statement that "[a]ll symptoms were resolving." *Id.* at 119. During an orthopedic appointment on November 28, 2017, Petitioner stated that following a "flu shot two years ago" she had experienced "multiple joint pain the next day, including the hips." *Id.* at 234. It is clear from the record that Petitioner's left shoulder aches and pain were accompanied by pain and stiffness in most of her other joints. Petitioner only distinguished her shoulder pain from her other complaints in her affidavit and motion pursuant to adjudicating this claim. Therefore, I do not find preponderant evidence that Petitioner's pain was limited to her left shoulder.

iv. Lack of Alternative Condition

Petitioner is unable to prevail on a Table claim without preponderant evidence of a 48-hour pain onset and that her symptoms were limited to the left shoulder. The last QAI factor prohibits compensation for a Table SIRVA if any alternative condition is present that could explain Petitioner's symptoms. Petitioner is also unable to satisfy this requirement. As I will discuss in more detail below, Petitioner was diagnosed with fibromyalgia by her PCP after describing her

symptoms and undergoing an examination.[27] Petitioner's expert disagreed with Petitioner's treating physician's diagnosis and argued that she suffered from SIRVA. After a review of Petitioner's medical records and affidavit, expert reports, medical literature, and the parties' arguments, I find that there is evidence of a condition present that would explain her symptoms.

b. Diagnosis

Petitioner's treater and PCP, Dr. Cohn, first mentioned fibromyalgia to Petitioner during an email exchange in January of 2016. He noted that her "symptoms [(including morning hand stiffness, hip and thigh pain, chest pain, achy knees and sore wrists)] may fit with this diagnosis, based on [her] prior normal labs and exams." Pet'r's Ex. 2 at 55. In February of 2016, Dr. Del Mar, another treating PCP, assessed Petitioner with adhesive capsulitis, lumbar radiculopathy, and "joint pain—fibromyalgia." *Id.* at 82. Dr. Del Mar noted Petitioner's belief that her vaccination and joint pain were related, but there is no indication that Dr. Del Mar shared that belief. *See id.* Dr. Del Mar's diagnosis was based on her physical exam of Petitioner that revealed right hip and lumbar tenderness with limited overhead reach. In fact, there is no evidence that any of Petitioner's treaters believed that Petitioner's pain or other symptoms were consistent with SIRVA or were related to a mechanical error during the administration of her vaccine. Alternatively, the medical record provides strong evidence that both of Petitioner's PCPs considered all of Petitioner's symptoms, including her multiple areas of joint pain, in identifying fibromyalgia as a differential diagnosis.

Petitioner's expert, Dr. Natanzi, opined that Petitioner had been misdiagnosed with fibromyalgia. He instead asserted that Petitioner had SIRVA based on "the lack of any alternative etiology for the acute development of [her] shoulder pain in the peri-vaccination period." Pet'r's Ex. 7 at 8. Dr. Natanzi then explained why he believed the alternative etiology proposed by Petitioner's treaters is inapplicable. He argued against fibromyalgia because the condition is defined by musculoskeletal achiness, stiffness, and tenderness. *See id.* In light of his discussion and dismissal of the fibromyalgia diagnosis, Dr. Natanzi's assertion that there is no alternative for consideration is incredulous. Indeed, Petitioner's initial post-vaccination complaint to a medical professional was a "[four] week aching in [her] shoulder [more than in] other joints." Pet'r's Ex. 2 at 10–11. Dr. Natanzi discounted this original complaint because of the timing discrepancy between Petitioner's post-vaccination reports of onset. However, Petitioner also complained of achy wrists, knees, and in the middle of her chest in January of 2016; she complained of hand stiffness and hand weakness and displayed tenderness in the right hip and lower lumbar area in February of 2016; and she complained of left elbow and hand stiffness in March of 2016. Pet'r's Ex. 2 at 35, 33, 80, 98–101. This collection of symptoms paints a clear presentation of the musculoskeletal achiness, stiffness and tenderness that would indicate Petitioner suffered from fibromyalgia, consistent with Dr. Natanzi's definition.

Dr. Natanzi also characterized Petitioner's shoulder pain as isolated and focal, to be distinguished from her episodic and secondary peripheral pain in other joints. He opined that Petitioner, who was 55 years old at the time of her vaccination, suffered from "typical wear and

[27] Dr. Del Mar also considered radiculopathy as a differential diagnosis. The QAIs list radiculopathy as an example of a condition or abnormality that, if present, could explain Petitioner's symptoms and preclude a Table SIRVA claim. 42 C.F.R. 100.3(10)(iv).

tear pains that surface in the latter decades of life." Pet'r's Ex. 7 at 9. Petitioner described her active lifestyle in her affidavit, including kayaking, fishing, hiking, and bowling. Pet'r's Ex. 4 at 2. It is unclear, according to Dr. Natanzi, at what age a person enters the latter decades of life. It is also unclear why in her mid-fifties, Petitioner would be unable sit or drive for more than thirty minutes or need a cortisone injection in her hip because of pain due to normal wear and tear. Without medical literature or additional evidence, I do not find this line of reasoning persuasive. Rather, I find Dr. Natanzi's arguments regarding Petitioner's age to be unnecessary and unfounded, and therefore, they did not influence my decision.

Alternatively, Dr. Abrams' opinion that Petitioner indeed suffered from fibromyalgia was based on the ACR's criteria with references to Petitioner's medical record. Post vaccination, Petitioner complained of pain in ten different locations on her body that kept her from sleeping and caused fatigue, leading to melancholy. I am persuaded by Dr. Abrams' opinion that, in sum, Petitioner's symptoms produced WPI and SS scores that would meet ACR's clinical definition of fibromyalgia. Dr. Abrams also argued that because Petitioner did not undergo an MRI, "[t]here is no objective evidence of SIRVA." Resp't's Ex. C at 3. Petitioner's lack of an MRI does not preclude a SIRVA diagnosis. Furthermore, the QAIs do not state that an MRI is required in SIRVA cases. That is a moot issue here, however. The breadth of evidence supporting fibromyalgia makes further discussion unnecessary.

While I agree with Dr. Abrams' fibromyalgia diagnosis, I am troubled by his assertions that obese patients are not as susceptible to a SIRVA. Dr. Abrams relied on one article that specifically noted the study's limited application to obese individuals. *See* Resp't's Ex. A4; *see also* Resp't's Ex. A at 9. He did not otherwise consider or discuss Petitioner's body type and weight distribution. This argument likewise has not influenced my decision.

Petitioner has not presented preponderant evidence that she suffered from a Table SIRVA, nor has she presented preponderant evidence that her injury is consistent with an off-Table shoulder injury caused by her vaccination. However, Petitioner has asserted some evidence that her shoulder injury was caused-in-fact by her vaccination, and she presented a theory of causation. Therefore, I will complete an *Althen* analysis.

c. Causation-in-fact

i. *Althen* Prong One: General Causation Theory

SIRVA is a well-known phenomenon in the Program. As previously noted, SIRVA is clearly defined by the Table and includes several exclusionary factors. These factors, if present, may prohibit a petitioner from bringing a Table claim, but they do not preclude an allegation that a petitioner suffered an off-Table shoulder injury caused by vaccination. It is true that Petitioner must present a causation theory in all off-Table cases. Petitioner's expert clearly explained in his report how shoulder injuries caused by vaccinations, including SIRVAs, occur by overpenetration of the needle into the bursa and/or rotator cuff, causing inflammation and resulting in "adhesive capsulitis and rotator cuff mediated pain." Pet'r's Ex. 7 at 9. Respondent argued that Petitioner's theory does "not provide preponderant evidence of a mechanism for *how* vaccinations can cause shoulder injuries." Resp't's Ex. A at 8. Respondent simultaneously argued that Petitioner's

overpenetration theory is merely "plausible," which is not the standard of proof in the Program. While Respondent is correct that plausibility is not the standard, I do not find Respondent's argument against the medically acceptable theory of SIRVA to be persuasive given the knowledge and understanding of SIRVA in the Program. I further find that even in the presence of a history of inflammation and dysfunction, Petitioner has presented preponderant evidence that the flu vaccine can cause an off-Table shoulder injury. and she has therefore satisfied prong one of *Althen*.

ii. *Althen* Prong Three: Temporal Relationship

During the Table claim analysis, I found that Petitioner has not presented preponderant evidence that her injury manifested within 48 hours of her vaccination. However, she did present evidence that her shoulder pain developed shortly thereafter, by mid-October, within the following several days after her October 14, 2015 vaccination. Although onset within 48 hours is required by the Vaccine Injury Table, onset in a cause-in-fact claim does not need to occur precisely within 48 hours. In *Jewell*, the chief special master found that although the petitioner was unable to establish onset within 48 hours of vaccination, the onset of her shoulder injury within 72 hours was a "medically appropriate temporal relationship." *Jewell v. Sec'y of Health & Hum. Servs.*, No. 16-0670V, 2017 WL 7259139, at *3 (Fed. Cl. Spec. Mstr. Aug. 4, 2017). Likewise in *Murray*, the petitioner did not establish that her shoulder pain occurred within 48 hours of vaccination, but the special master found that she "preponderantly demonstrated that her musculoskeletal shoulder symptoms began within a timeframe for which it is medically acceptable to infer causation-in-fact." *Murray v. Sec'y of Health & Hum. Servs.*, No. 17-01357V, 2022 WL 17829797, at *16 (Fed. Cl. Spec. Mstr. Oct. 27, 2022) (finding that while "a precise onset [was] impossible to pin down, the record [was] clear in placing onset no later than 'a few days' post vaccination," consistent with the petitioner's medical theory). Furthermore, the Federal Circuit has counseled that special masters should not set "hard and fast deadlines" when evaluating the appropriate timeframe for onset after vaccination. *Paluck v. Sec'y of Health & Hum. Servs.*, 786 F.3d 1373, 1384 (Fed. Cir. 2015). Accordingly, as Petitioner has presented evidence that shows she experienced the onset of shoulder pain within a few days of her vaccination, Petitioner has preponderately demonstrated that her shoulder symptoms began within a timeframe consistent with her causation theory.

iii. *Althen* Prong Two: Specific Causation

In *Capizzano*, the Federal Circuit explained that in some contexts, satisfaction of *Althen* prongs one and three can provide substantial support for evidence of specific causation to satisfy prong two. 440 F.3d at 1326. The Circuit found that if an appropriate temporal proximity, combined with a valid causation theory, demonstrates the logical conclusion that the injury was vaccine caused, then medical opinions of treating physicians to this effect "are quite probative." *Id.* However, the Circuit also cautioned that the second *Althen* prong "is not without meaning." *Id.* The Court explained that

> There may well be a circumstance where it is found that a vaccine *can* cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to conclude that the injury was actually caused by the vaccine. A claimant could satisfy the first and third prongs without satisfying the second prong when medical records and medical opinions do not suggest that the vaccine caused

> the injury, or where the probability of coincidence or another cause prevents the claimant from proving that the vaccine caused the injury by preponderant evidence.

Id. at 1327. Thus, it is well established that in terms of demonstrating specific causation, temporal association alone is not enough to satisfy a petitioner's burden of proof. *See, e.g.*, *Veryzer v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 344, 356 (2011) (explaining that "a temporal relationship alone will not demonstrate the requisite causal link and that petitioner must posit a medical theory causally connecting the vaccine and injury"); *A.Y. by J.Y. v. Sec'y of Health & Hum. Servs.*, 152 Fed. Cl. 588, 595 (2021); *Forrest v. Sec'y of Health & Hum. Servs.*, No. 10-032V, 2017 WL 4053241, at *18 (Fed. Cl. Spec. Mstr. Aug. 10, 2017); *Cozart v. Sec'y of Health & Hum. Servs.*, No. 00-590V, 2015 WL 6746616, at *18 (Fed. Cl. Spec. Mstr. Oct. 15, 2015), *aff'd*, 126 Fed. Cl. 488 (2016); *Crosby v. Sec'y of Health & Hum. Servs.*, No. 08-799V, 2012 WL 13036266, at *37 (Fed. Cl. Spec. Mstr. June 20, 2012).

In the present case, Petitioner has presented preponderant evidence that the flu vaccination can cause an off-Table shoulder injury. She has also presented preponderant evidence that her shoulder pain manifested within an appropriate time frame consistent with her medical theory to support vaccine causation. Petitioner has failed, however, to present preponderant evidence that she has an off-Table shoulder injury caused by vaccination. Therefore, her causation theory and the corresponding temporal relationship are inapplicable to her condition. Petitioner has not demonstrated how her causation theory, based on the injury that it contemplates, could be applicable to her symptoms that far exceed the scope of her shoulder. Petitioner's theory does not explain, or even consider, the many additional symptoms that she experienced contemporaneously with her shoulder injury. Indeed, the medical evidence and statements from Petitioner to her treaters overwhelming support a diagnosis of fibromyalgia,[28] but fibromyalgia is the not the alleged injury here. Furthermore, I am not a physician, and it is not my role to diagnose Petitioner. My role is to determine whether there is preponderant evidence that she suffered from the injury alleged. There is not. Therefore, Petitioner has not satisfied her burden under *Althen* prong two.

VII. Conclusion

Petitioner has undoubtedly suffered for many years as a result of her multiple joint pain and stiffness. However, when she sought appropriate medical care and reported this history to her physicians, they ultimately concluded that she was likely suffering from the systemic disorder fibromyalgia, rather than any shoulder condition. Petitioner has been unable to overcome that evidence with her expert evidence or otherwise. After considering the entire record, Petitioner has not established by preponderant evidence either that her October 14, 2015 flu vaccination resulted in a Table SIRVA or, alternatively, was the cause-in-fact of an off-Table shoulder injury, consistent with a SIRVA. Accordingly, Petitioner is not entitled to compensation. Therefore, her case is **DISMISSED**.[29]

[28] Respondent presented probative evidence in support of an alternative claim rebuttal. However, as Petitioner was unable to establish a *prima facie* case, that analysis is unnecessary. Such evidence was also considered in support of Drs. Cohn and Del Mar's opinions that Petitioner suffered from fibromyalgia.

[29] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.

IT IS SO ORDERED.

s/Herbrina D. Sanders
Herbrina D. Sanders
Special Master